IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

STEPHANIE YATES,

Plaintiff,

Case No. 3:09 oe 40023

-vs-

MEMORANDUM OPINION

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.,

Defendant.

KATZ, J.

Stephanie Yates, who is a New York resident, sued Ortho-McNeil Pharmaceutical, Inc., Alza Corporation, Johnson & Johnson Pharmaceutical Research and Development, LLC, and Johnson & Johnson in the Erie County (New York) Supreme Court. Ms. Yates alleged she had been prescribed the Ortho Evra® birth control patch which allegedly caused her to have a stroke. The Defendants moved for summary judgment. (Doc. 48). Ms. Yates filed a response (Doc. 57), and the Defendants filed a reply. (Doc. 65). Both parties have filed sur-replies. (Docs. 85, 86).

I. Jurisdiction

The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332.

II. Facts

On September 4, 2008, Ms. Yates sued the Defendants asserting that after she had been prescribed the Ortho Evra® birth control patch, she suffered a stroke on April 24, 2005. Ms. Yates alleged the following causes of action: 1) strict liability in tort-failure to warn; 2) strict liability in tort-manufacturing defect; 3) negligence; 4) breach of implied warranty; and 5) breach of express warranty.

The Defendants removed the case to the United States District Court for the Western District of New York. Following removal, the case was transferred to the undersigned as related to the Ortho Evra® litigation by the Judicial Panel on Multidistrict Litigation. *In re Ortho Evra Prods. Liab. Litig.*, 1:06 cv 40000 MDL 1742 (N.D. Ohio).

Ms. Yates first received counseling concerning different birth control options, including the Ortho Evra® patch, on November 3, 2004. Before then, Ms. Yates was unaware of the Ortho Evra® patch either from advertisements or from personal contacts. Ms. Yates admittedly had never heard of the Ortho Evra® patch until she met with OB/GYN Associates of Western New York in November 2004.

Jennifer Anne Smith is a licensed physician's assistant and, since 2001, specialized in obstetrics and gynecology at OB/GYN Associates. Her job included seeing, examining, diagnosing, and treating women for both routine gynecology examinations and gynecological problems. Ms. Smith also prescribes medicines, including hormonal contraceptives. Her knowledge and expertise concerning contraceptives comes from multiple sources, including her medical training, published literature in professional journals, professional conferences, continuing medical education classes, the *Physicians' Desk Reference*, office handouts, and product information provided by company sales representatives.

According to her deposition testimony, Ms. Smith decides on what medications to prescribe based upon her clinical experience, knowledge of product, and patient assessment. With regards to birth control, Ms. Smith considers not only the medication, but also the circumstances of the particular patient, including the patient's health, physical condition, personal and family medical history, and potential contraindications. Ms. Smith weighs the risks and benefits of the

medicine for the particular patient. Ms. Smith prescribes a birth control product based upon her independent medical judgment and her conclusion that the medicine will be safe and effective for the particular patient. Ms. Smith admittedly recognizes that all medicines have potential risks and only prescribes medications if she is satisfied that "the patient is more likely to be helped than hurt by the product."

Over the years, Ms. Smith has prescribed many different hormonal birth control products, which she concedes have risks, including an increased risk of blood clots, deep vein thrombosis, heart attack, and stroke. She also acknowledges that warnings about those risks have been included in the package inserts for healthcare professionals and patients for many years, long before she prescribed the Ortho Evra® patch to Ms. Yates in 2005. Ms. Smith stated she has counseled patients concerning these risks for many years.

Ms. Smith was and still is familiar with the risks and benefits of the Ortho Evra® patch. This knowledge existed even before she prescribed the Ortho Evra® patch to Ms. Yates. Based upon her experience, Ms. Smith believes that the Ortho Evra® patch is easy to use and has a high compliance rate. Ms. Smith was familiar with the risks and contraindications set forth in the Ortho Evra® package insert, including the Detailed Patient Labeling, when she prescribed the Ortho Evra® patch to Ms. Yates. Based upon her clinical judgment, Ms. Smith feels that Ortho Evra® is a reasonable, safe, and effective birth control method for some patients, and continues to prescribe the product.

On November 3, 2004, Ms. Yates was seventeen years old. She went to OB/GYN Associates in order to be placed on birth control because of "[s]evere menstrual cramps" and

because she was sexually active. Ms. Yates's mother, Judy Yates, did not accompany her daughter to this meeting.

On that date, Ms. Smith counseled Ms. Yates concerning the options, risks, and benefits of the various birth control products on the market. Ms. Smith's office notes state she discussed the risks, benefits, side effects of various contraceptive options. Ms. Smith's habit and custom was to discuss the risks involved, including breakthrough bleeding, headaches, nausea, breast tenderness, moodiness, blood clots, and stroke. She also discussed the benefits of preventing an unplanned pregnancy and the relief from menstrual cramping. Ms. Yates concedes she was counseled concerning the risk of a stroke and clotting associated with the Ortho Evra® patch.

Ms. Yates selected Depo-Provera because the injections were only required at three-month intervals. Ms. Yates received her first Depo-Provera injection on November 26, 2004. She never returned for the second shot, and on March 3, 2005, she told nurse Christine Palbo that she decided to discontinue Depo-Provera due to weight gain. Ms. Yates stated she wanted to try the Ortho Evra® patch. Ms. Yates complained of heavy or irregular bleeding, which was a recognized side effect of the Depo-Provera injection, and was a common complaint by Depo-Provera users. Nurse Palbo consulted Ms. Smith concerning Ms. Yates's request to change her birth control method. Ms. Smith approved the change to the Ortho Evra® patch, starting March 6, 2005. However, due to continuous bleeding and a possible pregnancy, Ms. Yates did not begin using the Ortho Evra® patch until April 17, 2005.

Ms. Smith's deposition testimony stated that when a patient decides to change her birth control method, it is her standard practice to re-counsel the patient concerning the risks of the product, including the risk of a stroke. On April 15, 2005, two days before Ms. Yates started

using the patch, Ms. Smith advised Ms. Yates that the Ortho Evra® patch might be less effective due to her weight. Ms. Smith, per her routine, again reminded Ms. Yates concerning the potential risks and side effects associated with the use of the Ortho Evra® patch. Ms. Yates failed to perform any research regarding Ortho Evra® because she trusted the medical advice she was given. Ms. Yates admitted in her deposition testimony she would still have used the Ortho Evra® patch if she read the warning in the Detailed Patient Labeling, including the warnings about the risk of stroke.

Judy Yates admitted knowing that her daughter was using the Ortho Evra® patch. In fact, Judy Yates accompanied her daughter to the facility and sat in the waiting room when the product was prescribed. She was also aware of the product samples provided to her daughter. Ms. Yates did not relate the counseling provided at OB/GYN Associates to her mother, nor did she relate the potential risks associated with the patch. Judy Yates, however, saw the package of samples, including an insert with instructions. Judy Yates never read, nor recalls reading, the instructions to the product, nor did she see her daughter read them. At her deposition, defense counsel read the warnings about the risk of stroke in Ortho Evra®'s Detailed Patient Labeling. Judy Yates testified that even if she had read the product warnings, she would have permitted her daughter to use the Ortho Evra® patch.

Thus, before Ms. Yates's stroke, Ms. Smith was aware that the Ortho Evra® patch could cause a stroke. Ms. Smith was familiar with the language of Ortho Evra®'s FDA approved package insert, including the Detailed Patient Labeling, which warned about the risk of stroke. Ms. Smith counseled Ms. Yates concerning the risks of the product, including the risk of a stroke,

on multiple occasions. Ms. Smith concluded that Ortho Evra® was a safe and effective product for Ms. Yates. Further, Ms. Smith continues to prescribe the Ortho Evra® patch to patients.

II. Summary Judgment

Summary judgment is proper where "there is no genuine dispute as to any material fact" and the moving party "is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A party asserting a genuine issue of material fact must support the argument either by "citing to particular parts of materials in the record" or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1). The Court views the facts in the record and reasonable inferences that can be drawn from those facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The Court does not weigh the evidence or determines the truth of any matter in dispute. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).

The party requesting summary judgment bears an initial burden of demonstrating that no genuine issue of material fact exists, which the party must discharge by producing evidence to demonstrate the absence of a genuine issue of material fact or "by showing . . . that there is an absence of evidence to support the nonmoving party's case." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–25 (1986) (internal quotation marks omitted). If the moving party satisfies this burden, the nonmoving party "may not rest upon its . . . pleadings, but rather must set forth specific facts showing that there is a genuine issue for trial." *Moldowan v. City of Warren*, 578 F.3d 351, 374 (6th Cir. 2009) (citing Rule 56 and *Matsushita*, 475 U.S. at 586). The party opposing the summary judgment motion must present sufficient probative evidence supporting its claim that

disputes over material facts remain; evidence that is "merely colorable" or "not significantly probative" is insufficient. *Anderson*, 477 U.S. at 248–52.

III. Failure to Warn Claim

The Defendants have moved for summary judgment on Ms. Yates's failure to warn claim. The parties agree that this is a "pre-label" Ortho Evra® case. Ortho Evra® was approved by the FDA in 2001 and placed into the United States market in 2002. Ms. Yates was prescribed the Ortho Evra® patch in April 2005. The warning label for the product was subsequently changed, thus creating the distinction between a "pre-label" and "post-label" case. As Ms. Yates recognizes, this Court has already dismissed numerous "pre-label" cases. (Doc. 58, p. 2). Ms. Yates has raised several arguments which she feels prevents the grant of summary judgment for the Defendants in this case.

Under New York law, when a plaintiff brings a failure to warn claim against a manufacturer, "'a plaintiff must demonstrate that the warning was inadequate and that the failure to adequately warn of the dangers . . . was a proximate cause of his or her injuries.'" *Krasnopolsky v. Warner–Lambert Co.*, 799 F. Supp. 1342, 1346 (E.D. N.Y. 1992) (quoting *Glucksman v. Halsey Drug Co.*, 553 N.Y.S.2d 724, 726 (N.Y. App. Div. 1990)); *see also Anderson v. Hedstrom Corp.*, 76 F. Supp. 2d 422, 439–44 (S.D. N.Y. 1999).

With respect to the adequacy of warnings, the informed intermediary doctrine applies to prescription drugs. *Erony v. Alza Corp.*, 913 F. Supp. 195, 199 (S.D. N.Y. 1995); *see also Fane v. Zimmer, Inc.*, 927 F.2d 124, 129–30 (2d Cir. 1991); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 259–60 (E.D. N.Y. 1999). Under this doctrine, "[t]he manufacturer of a prescription drug has a duty to warn of all potential dangers which it knows or should know, and must take such steps as

are reasonably necessary to bring that knowledge to the attention of the medical profession." *Glucksman*, 553 N.Y.S.2d at 726. The manufacturer's duty of adequate warning is therefore fulfilled by providing sufficient information of the product's risk to the treating physician, rather than directly to the patient. *See Martin v. Hacker*, 628 N.E.2d 1308, 1311–12 (N.Y. 1993). Under New York law, a physician's assistance, such as Ms. Smith, is licensed to prescribe medications and qualifies as a learned intermediary. *See* N.Y. Public Health Law §§ 3703, 6542.

In the Ortho Evra® package insert which was in existence when Ms. Yates used the product, the following warning, among others, was included:

> **RISKS OF USING HORMONAL CONTRACEPTIVES, INCLUDING ORTHO EVRA®**
>
> . . .
>
> **2. Heart Attacks and Strokes**
>
> Hormonal contraceptives, including ORTHO EVRA®, may increase the risk of developing strokes (blockage or rupture of blood vessels in the brain) and angina pectoris and heart attacks (blockage of blood vessels in the heart). Any of these conditions can cause death or serious disability.
>
> Smoking and the use of hormonal contraceptives including ORTHO EVRA® greatly increase the chances of developing and dying of heart disease. Smoking also greatly increases the possibility of suffering heart attacks and strokes.

Because the document explicitly warned that the product could cause strokes, the Court finds that the warning is sufficient to meet the Defendants' duty to provide adequate warnings to treating physicians regarding a possible risk of the product. *Martin*, 628 N.E.2d at 1311–12. Any subsequent modification of the warnings does not impact the fact that the warning which existed at the time Ms. Yates received the product explicitly forewarned of the possibility of a stroke.

The record further establishes that before Ms. Yates's stroke, Ms. Smith was aware the Ortho Evra® patch could cause a stroke. Ms. Smith was familiar with the language of Ortho Evra®'s FDA approved package insert which warned about the risk of stroke. Ms. Smith

informed Ms. Yates concerning the risks of the product, including the risk of stroke, on multiple occasions. It was Ms. Smith's medical opinion that Ortho Evra® was a safe and effective product for Ms. Yates. Ms. Smith continues to prescribe the Ortho Evra® patch to patients.

Ms. Yates contends the warnings she received were insufficient because she was an unemancipated minor at the time the medical warnings were given. Because New York does not allow a minor to be competent so as to consent to the use of birth control, Ms. Yates asserts she could not have given an informed consent regarding the Ortho Evra® patch. Although the parties agree New York does not have a law addressing a minor's competency to consent to taking birth control, the facts establish that Ms. Yates's mother consented to her daughter's use of the drug.

Judy Yates admitted knowing her daughter was using the Ortho Evra® patch. Judy Yates accompanied her daughter to OB/GYN Associates and sat in the waiting room while the product was prescribed. She was also aware of the product samples provided to her daughter. Ms. Yates did not relate the counseling provided at OB/GYN Associates to her mother, nor did she relate the potential risks associated with the patch. Judy Yates did see the package of samples of the Ortho Evra® patch which her daughter was given, including an insert with instructions. Judy Yates admittedly never read, nor recalled reading, the instructions to the product, nor did she see her daughter read them. At her deposition, after having been read some of the warnings, including the risk of stroke from Ortho Evra®'s Detailed Patient Labeling, Judy Yates testified that even if she had read the product warnings, she would have permitted her daughter to use the Ortho Evra® patch. Thus, even assuming Ms. Yates, as a minor, did not have the capacity to consent to the treatment, Judy Yates was fully aware that her daughter was taking the product and conceded she would still allow her daughter to take the product despite the possibility the product could cause a

stroke. Judy Yates's testimony regarding her awareness of the drug and her daughter's use of the product, along with her approval of the use of the drug despite its possible side effects, constitutes parental approval for Ms. Yates to take the Ortho Evra® patch.

Ms. Yates contends she lacked a sufficient understanding regarding the patch. She also asserts that she did not receive a medication guide in her free samples of the patch. The manufacturer's duty of adequate warning is fulfilled by providing sufficient information of the product's risks to the treating physician, not the patient. *See id*. Whether Ms. Yates, as she now claims, did not understand the ramifications of the product, or failed to get a medication guide with the samples, is irrelevant. The Defendants' duty to warn is to the physician and not the patient. *Id*. Ms. Smith was aware of the warnings and risks regarding the patch before she prescribed the product to Ms. Yates. The Defendants have met their burden to warn. *Id*. Therefore, the Defendants' motion for summary judgment regarding Ms. Yates's failure to warn claim is granted.

IV. Remaining Claims

Regarding Ms. Yates's claims of manufacturing defect, negligence, breach of implied warranty, and breach of express warranty, the Defendants have moved to dismiss these claims for failing to state a claim for relief. (Doc. No. 48, pp. 23–24). The Defendants argue that these theories of recovery are based on conclusory allegations which do not satisfy the requirements of Federal Rule of Civil Procedure 8(a)(2), *Ashcroft v. Iqbal*, 556 U.S. 662, 677–80 (2009), and *Bell Atlantic Corp. v. Twomby*, 550 U.S. 544, 555–56 (2007).

The motion to dismiss is denied. Ms. Yates's claims are more than sufficient to satisfy the requirements of Rule 8(a)(2), *Iqbal*, and *Twomby*.

V. Motion to Amend Complaint

Ms. Yates states that should this Court decide that more specificity is required based on an expert witness's report, then she requests leave to amend her complaint so the complaint is in "conformity" with the "facts stated" in the report, "as well as the facts that have been adduced through discovery." (Doc. 58, pp. 39–40).

Federal Rule Civil Procedure 15(a)(2) provides that a court may freely grant leave to amend a pleading when justice so requires in order to ensure that a case is tried on its merits "rather than [on] the technicalities of the pleadings." *Moore v. City of Paducah*, 790 F.2d 557, 559 (6th Cir. 1986). "In deciding whether to grant a motion to amend, courts should consider undue delay in filing, lack of notice to the opposing party, bad faith by the moving party, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party, and futility of amendment." *Brumbalough v. Camelot Care Ctrs., Inc.*, 427 F.3d 996, 1001 (6th Cir. 2005).

Upon review, the motion to amend is denied. Ms. Yates's brief fails to tender a proposed amended complaint to the Court for the Court's examination. Even without a tendered complaint, the motion fails to proffer the barest of explanations as to how or to what issues and facts Ms. Yates would seek to add.

In addition, any amendment at this stage of the litigation would be extremely prejudicial to the Defendants. The original complaint was filed on September 4, 2008. Over four years later, Ms. Yates makes a vague request to amend the complaint if this Court, in essences, declines to accept the opinion of one of her expert witnesses. That is not how Rule 15(a)(2) works. The

motion is simply an attempt by Ms. Yates to avoid the grant of summary judgment to the Defendants.

Ms. Yates has had years to be able to amend her complaint. Discovery has been conducted and any motion to amend the complaint now that the summary judgment motion has been filed would be extremely prejudicial to the Defendants. Finally, the Court's opinion establishes that the requested amendment would be futile. *Id*. For these reasons, Ms. Yates's request to amend her complaint is denied.

VI. Conclusion

Accordingly, Plaintiff's motion to amend her complaint (Doc. 58) is denied; the Defendants' motion for summary judgment on the failure to warn claim (Doc. No. 48) is granted; and the Defendants' motion to dismiss Plaintiff's manufacturing defect, negligence, breach of implied warranty, and breach of express warranty claims (Doc. No. 48) is denied.

IT IS SO ORDERED.

S/ *David A. Katz*
DAVID A. KATZ
U. S. DISTRICT JUDGE